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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,938	MORITA ET AL	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/20/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-11 and 15-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11 and 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *04 June 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/11/05, 4/18/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In view of the appeal brief filed on 3/20/06, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

Claims examined on the merits examined on the merits are 7-11 and 15-19, which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 7-9, 11, 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti et al (5,855,610) (newly applied).

The claims are drawn to a method for regenerating cardiovascular tissue by seeding cells on a matrix comprising sponge configured to regenerate cardiovascular tissue and made of bioabsorbable material and a reinforcement made of a bioabsorbable material, culturing the cells until the matrix surface is completely covered with cells, and embedding the matrix *in vivo* for generating cardiovascular tissue.

Vacanti et al disclose reconstruction and augmentation of flexible, strong connective tissue such as arteries and heart valves (col 1, lines 4-7). Objectives include producing tissue engineered constructs having improved mechanical strength and flexibility, making valves and vessels which can withstand repeated stress and strain, and improving yields of engineered tissues (col 2, lines 33-42). Structures are created by seeding a fibrous or porous polymeric matrix with cells (col 2, lines 65-67) to form tissues having structural elements such as heart valves and blood vessels (col 3, line 2-3). For a tissue to be constructed, successfully implanted and function, matrices must have sufficient surface area and exposure to nutrients such that cellular growth and differentiation can occur prior to the ingrowth of blood vessels following implantation (col 3, lines 26-29). The matrix acts as a scaffold providing a three-dimensional space for cell growth. The matrix functions as a template providing structural cues for tissue development (col 3, lines 10-15). The scaffold determines the limits of tissue growth and thereby determines the ultimate shape of a tissue engineered construct. The cells on the matrix proliferate only to the edges of the matrix (col 3, lines 20-

23). The matrix can be formed of polymers having a fibrous structure, which has sufficient interstitial spacing to allow for free diffusion of nutrients and gases to cells attached to the matrix surface. The spacing can be in a range of 100 to 300 microns, although closer spacings can be used if the matrix is implanted, blood vessels allowed to infiltrate the matrix, then the cells are seeded into the matrix (col 3, lines 42-49). The matrix can be sponge like (col 3, line 51), and can be a polyvinyl alcohol sponge (col 4, lines 25-27). The matrix can be formed of a biodegradable polymer such as poly(lactide) (PLA), poly(glycolic acid) (PGA) or poly(lactide-co-glycolide) (PLGA) (col 4, lines 8-11). Forms of lactic acid used to prepare PLA polymers can be L(+), D(-) or DL (col 4, lines 45-49). The overall matrix configuration is dependent on the tissue, which is to be constructed or augmented. The shape of the matrix can be obtained using struts that impart resistance to mechanical forces to yield the desired shape such as heart valve leaflets and tubes (col 3, lines 62-67). The struts can be biodegradable, and formed of the polymer material used to form the matrix to provide a matrix having sufficient strength to resist the necessary mechanical forces (col 5, lines 38-48). In Example 1 (beginning in col 7, line 60), a tissue engineered heart valve is produced. A PGA fiber based matrix is seeded with a mixed cell population containing myofibroblasts and endothelial cells and grown in culture until the myofibroblasts reached confluence. Then endothelial cells are seeded onto the surface of the fibroblast/mesh construct and grown into a single monolayer. The

tissue engineered heart valve resembled native valve tissue. The construct was implanted in sheep to determine if the construct had the required pliability and mechanical strength (col 8, lines 21-23). In Example 2 (beginning in col 8, line 45), a tissue engineered vascular structure is prepared. A PGA tubular construct is seeded with a smooth muscle cells and fibroblasts. After the fibroblasts and smooth muscle cells have grown to confluence, endothelial cells are seeded on the construct and the construct placed in culture (col 8, lines 50-56). Endothelially lined smooth muscle/fibroblast tubes were created (col 9, lines 5-7).

Vacanti et al disclose producing blood vessels, arteries and heart valves (cardiovascular tissue) using steps as claimed by seeding cells on a matrix made of bioabsorbable material configured to regenerate the tissue, culturing the cells on the matrix (Examples 1 and 2), and embedding the matrix *in vivo*, i.e. implanting the matrix containing tissue formed (col 2, lines 41-42, and col 8, line 21). It would have been obvious to reinforce the matrix with a bioabsorbable material since Vacanti et al disclose that the matrix must have sufficient mechanical strength, and that the mechanical strength can be obtained by providing the matrix with biodegradable struts to form a matrix having sufficient strength to resist mechanical forces. It would have been obvious to use the biodegradable polymer matrix of Vacanti et al in the form of a sponge since Vacanti et al disclose that the matrix can be sponge like (col 3, line 51) and the use of a polyvinyl alcohol sponge (col 4, lines 25-26). Growing cells to

confluence and forming a monolayer of endothelial cells on the matrix as in Example 1 of Vacanti et al (col 8, lines 12-15) will produce a matrix completely covered with cells as required in claim 7. Growing cells to confluence and culturing as in Example 2 of Vacanti et al will also result in the matrix completely covered with cells. Producing a blood vessel as in claim 8 and a cardiac valve as in claim 9 is disclosed by Vacanti et al. In Examples 1 and 2, Vacanti et al use a mixed cell culture (col 8, lines 8, and 49-50) as in claim 11. Vacanti et al disclose using materials that are bioabsorbable (col 4, lines 9-15 and 41-49) as in claim 15. A pore diameter of 100 μm is encompassed by the pore diameter range of about 5 μm to about 100 μm of claim 19, and 100 μm would have been obvious from Vacanti et al disclosing the matrix containing interstitial spacing of 100 to 300 microns for diffusion of nutrients and gases to cells (col 3, line 46).

Response to Arguments

The argument in the brief concerning tissue engineering and tissue requiring elasticity not being disclosed is unpersuasive with respect to Vacanti et al since Vacanti et al is clearly performing tissue engineering, and the tissue produced will have elasticity the same as tissue produced by the claimed process. Furthermore, the present claims do not require producing tissue having a certain amount of elasticity.

The argument in regard to the matrix of the claims being completely covered with cells is unpersuasive since Vacanti et al

disclose Examples 1 and 2 culturing under conditions that will completely cover the matrix. In particular, in Example 1, a monolayer of endothelial cells is formed as in the present specification (page 11, line 19). Additionally, growing a mixed culture to confluence as in Examples 1 and 2 (after 3 weeks in Example 2) will result in the matrix being completely covered with cells as in the present specification when culturing a mixed culture (page 12, lines 22-25).

The argument concerning the use of a bioabsorbable reinforcement is unpersuasive since Vacanti et al disclose the need for mechanical strength, and using struts made of a biodegradable synthetic polymer to provide the matrix with mechanical strength.

As to the argument concerning *ex vivo* tissue engineering, Vacanti et al disclose *ex vivo* tissue engineering since in Examples 1 and 2 culturing is *in vitro*. In any event, claim 7 does not require culturing to be *ex vivo*, and culturing can be *in vivo* to produce the matrix surface completely covered with cells.

The argument concerning combining references does apply to the present rejection since no references are combined with Vacanti et al.

The argument concerning unexpected results of the invention is unpersuasive since the tissue engineering process suggested by Vacanti et al will produce results the same as obtained from the claimed method.

Claim Rejections - 35 USC § 103

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti et al as applied to claims 7-9, 11, 15 and 19 above, and

further in view of Fofonoff et al (5,882,929) taken with Cox (6,719,789) or Love (5,509,930) (all newly applied).

The claim requires pericardium tissue as the cardiovascular tissue regenerated.

Fofonoff et al disclose (col 20, lines 53-67) seeding a matt with cells to repair, reconstruct or replace tissue, which can be pericardial tissue (colo 20, line 66).

Cox discloses (col 24, lines 39-60) producing a heart valve using pericardium tissue.

Love discloses (col 1, lines 40-42, and col 10, lines 8 and 22) using pericardium tissue to produce a prosthetic heart valve.

When producing a heart valve by tissue engineering as disclosed by Vacanti et al, it would have been obvious to produce pericardium tissue to form the heart valve as suggested by Fofonoff et al producing pericardium tissue using a cell seeded matt, and Cox or Love using pericardium tissue to produce heart valves. Pericardium tissue would have been expected to be an effective tissue for producing a heart valve since this is a known tissue for producing a prosthetic heart valve.

Claim Rejections - 35 USC § 103

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti et al as applied to claims 7-9, 11, 15 and 19 above, and further in view of Vyakarnam et al (6,534,084), and if necessary in further view of the Japanese patent.

The claims require producing an artery, a vein or a cardiac valve wherein the sponge comprises lactic acid-caprolactone copolymer and the reinforcement comprises polylactic acid or polyglycolic acid.

Vyakarnam et al disclose foam structures that can be composed of copolymers of lactide such as a poly(L) lactide-co-E-caprolactone (col 6, line 45, col 9, lines 53-55 and col 12, lines 5-9), and which can be used to regenerate tissue such as tubular structures such as vascular grafts (col 3, lines 1 and 20-21, and col 9, lines 19-24). The pore size of the foam can be 30-50 Tm or 100-200 Tm (paragraph bridging cols 4 and 5). The foam can be reinforced with fibers (col 6, line 40) made of calcium phosphate.

The Japanese patent discloses a reinforced collagen sponge for implanting in tissue. The sponge is reinforced with fibers made of poly-L-lactic acid.

When using biodegradable polymer struts for reinforcement and a biodegradable sponge as a matrix as suggested by Vacanti et al as set forth above, it would have been obvious to use polylactic acid or polyglycolic acid as the polymer forming the struts since Vacanti et al disclose these as biodegradable polymers that can be used to form the struts and sponge. It would have been further obvious to use lactic acid-caprolactone copolymer to form the sponge that can be the matrix of Vacanti et al since Vacanti et al disclose that the matrix can be formed of polylactic acid or poly(caprolactone) (col 4, lines 9-11), and Vyakarnam et al disclosing foam structures such as vascular

grafts formed of poly(L) lactide-co-E-caprolactone for use in tissue engineering. If needed, the Japanese patent would have suggested reinforcement of a sponge with polylactic acid fibers.

Claim Rejections - 35 USC § 103

Claims 7, 8 and 11 are are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton et al (5,863,531).

The claimed invention is described above.

Naughton et al disclose producing tissue *in vitro* by seeding cells on a three-dimensional framework having interstitial spaces, which can be shaped to assume the conformation of natural organs and their components (col 4, lines 63-64). The three-dimensional framework can be formed of biodegradable matrices such as collagen sponge (col 9, line 42), or polyglycolic acid or polylactic acid and copolymers thereof (col 9, lines 59-62). Tubular tissue structures can be formed (col 6, lines 55-60 and col 22, line 41) such as in the form of blood vessels (col 24, line 33), arteries (col 24, line 37) or veins (col 25, line 24). Implantation of a valve is also disclosed (col 19, line 49). Stromal cells such as fibroblasts or stromal cells in combination with other cells such as endothelial cells or smooth muscle cells (col 4, lines 23-28, and col 11, lines 9-25) are grown *in vitro* on the framework where the stromal cells and their naturally secreted extracellular matrix proteins and connective tissue proteins envelop the framework to form a three dimensional living stromal tissue (col 4, lines 30-44, col 7, lines 51-60, and col 11, line 64). Since the inner walls of arteries are rich in elastin, an arterial

stroma should contain a high concentration of smooth muscle cells which elaborate elastin (col 13, lines 28-31). The elastin provides strength and elasticity required of blood vessels *in vivo* (col 4, lines 2-9). Once the three dimensional tissue has reached the appropriate degree of growth, tissue-specific cells are inoculated on the stromal tissue, and can be grown on the stromal tissue *in vitro* to form a cultured counterpart of the native tissue prior to implantation *in vivo* (paragraph bridging cols 13 and 14, and col 14, lines 5-10). The cells chosen for inoculation depend on the tissue to be produced such as epithelium, endothelium and smooth muscle (col 14, lines 13-16). When producing arties, fibroblast cells and smooth muscle cells can be cultured to subconfluence on separate frameworks, the frameworks combined and the smooth muscle cells proliferated to produce elastin to simulate natural arterial walls. Thereafter, endothelial cells are seeded on top of an upper, elastin-rich layer, and incubated until they form a confluent layer (paragraph bridging cols 24 and 25, and col 25, lines 11-15).

When producing tubular tissue structures such are arteries, veins, blood vessels that are cardiovascular tissue as disclosed by Naughton et al, it would have been obvious to use collagen sponge as the framework in which cells are cultured to produce the tissue as suggested by Naughton et al (col 9, line 60). The collagen sponge is a sponge matrix as required by the present claims, and the method disclosed by Naughton et al when using collagen sponge is the same presently claimed. The extracellular matrix containing elastin

produced during culturing to form the stromal tissue will result in a bioabsorbable material that provides reinforcement as required by the present claims since Naughton et al disclose that elastin is a necessary component of blood vessels and provides strength (col 4, line 5) to the vessels, and is normal component of arteries (col 13, lines 28-31). After culturing tissue-specific cells on the stromal tissue contained by the collagen sponge, the sponge surface will be completely covered with cells since Naughton et al disclose that the tissue produced is a counterpart of native tissue prior to implantation (col 14, lines 7-10), and disclose culturing seeded endothelial cells on a elastin-rich layer to form a confluent layer (col 25, lines 13-15). A collagen sponge that is not completely covered with tissue formed by culturing the tissue-specific cells will not be a counterpart of native tissue. Naughton et al suggest a blood vessel (col 24, line 33) as required by claim 8, and a mixed cell culture (col 8, lines 16-17, and col 11, lines 9-15) as required by claim 11.

Response to Arguments

Applicants urge that Naughton et al disclose the framework being "substantially enveloped" by the cells, which is not completely covering a matrix with cells as claimed. However, Naughton et al also disclose that the stromal cells "envelop" the framework (col 11, line 64). Since "substantially" is not recited, Naughton et al intend that the framework can be completely covered with stromal cells as an alternative to being "substantially enveloped". In any event, the

framework being substantially enveloped as disclosed by Naughton et al is only in regard to growing stromal cells on the framework. After growing tissue specific cells on the stromal tissue resulting from growing stromal cells on the framework, the framework will be completely covered with cells since Naughton et al disclose obtaining a cultured counterpart of native tissue (col 14, lines 6-8), obtaining a confluent layer of endothelial cells (col 25, lines 8-10), and an elastin-rich stromal culture lined with endothelium (col 25, lines 18-20). The present claims do not exclude culturing stromal cells on the matrix followed by culturing tissue-specific cells as disclosed by Naughton et al. The present specification discloses (page 11, lines 7-19) culturing fibroblasts (stromal cells) on the matrix, and then culturing endothelial cells to form a monolayer.

Applicants' argument concerning elasticity is unpersuasive since the claims do not require an elasticity different than obtained by Naughton et al. The claims encompass cells that produce a high content of elastin as is apparent by claim 11 reciting "smooth muscle cells" as cells that can be used in a mixed cell culture.

Applicants argue that Naughton et al teach away from using artificial materials to provide strength and elasticity (col 4, lines 2-6). However, Naughton et al do not teach that artificial materials should be excluded, but that the presence of elastin provides better results than when elastin is not present since elastin is present in the natural counterpart. In any event, the present claims do not require the reinforcement to be with an artificial material. The

bioabsorbable material used for reinforcement as claimed can be an extracellular matrix containing elastin as disclosed by Naughton et al. The presently claimed invention will not produce results unexpectedly different than obtained by Naughton et al. Vyakarnam et al, Hinsch et al and the Japanese patent are not applied in the present rejection, and arguments concerning these reference are moot with respect to the present rejection.

Claim Rejections - 35 USC § 103

Claim 9, 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton et al as applied to claims 7, 8 and 11 above, and further in view of Vacanti et al.

The claimed invention, Naughton et al and Vacanti et al are described above.

It would have been obvious to use the procedure of Naughton et al to produce a heart valve as in claim 9 in view of Vacanti et al producing vascular structures or heart valves by a procedure similar to that of Naughton et al. Using bioabsorbable materials of claim 15 to produce a sponge instead of from collagen and to produce a reinforcement in addition to extracellular matrix containing elastin in Naughton et al would have been suggested by Vacanti et al using such materials to produce a biodegradable sponge-like matrix and a biodegradable reinforcement (struts) in a procedure similar to that of Naughton et al. Since Vacanti et al can use smooth muscle cells that produce elastin (col 8, line 50), it would have been apparent that reinforcement can be desirable even when elastin is present. A pore

size in the range of claim 19 would been obvious from Vacanti et al disclosing spacings of 100 to 300 microns (col 3, line 46).

Claim Rejections - 35 USC § 103

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 9 and 15 above, and further in view of Fofonoff et al taken with Cox or Love.

The claimed invention and references are described above.

When producing a heart valve by the procedure of Naughton et al as suggested by Vacanti et al as set forth above, it would have been obvious to produce pericardium tissue to form the heart valve as suggested by Fofonoff et al producing pericardium tissue using a cell seeded matt, and Cox or Love using pericardium tissue to produce a heart valve. Pericardium tissue would have been expected to be an effective tissue for producing a heart valve since this is a known tissue for producing a prosthetic heart valve.

Claim Rejections - 35 USC § 103

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 9, 15 and 19 above, and further in view of Vyakarnam et al, and if necessary in further view of the Japanese patant.

The invention and references described above.

When modifying Naughton et al as suggested by Vacanti et al as set forth above, it would have been obvious to use polylactic acid or polyglycolic acid as the polymer forming the struts since Vacanti et al disclose these as biodegradable polymers that can be used to form

the struts and sponge. It would have been further obvious to use lactic acid-caprolactone copolymer to form the sponge that can be the framework of Naughton et al as suggested by Vacanti et al since Vacanti et al disclose that the matrix can be formed of polylactic acid or poly(caprolactone) (col 4, lines 9-11), and Vyakarnam et al disclose foam structures such as vascular grafts formed of poly(L) lactide-co-E-caprolactone for use in tissue engineering. If needed, the Japanese patent would have suggested reinforcement of a sponge with polylactic acid fibers.

Response to Arguments

As set forth above, Naughton et al completely cover the framework with cells. Even if Vyakarnam et al does not completely cover the foam structure, this does not prevent completely covering the structure as suggested by Naughton et al.

Applicants urge that there is not motivation to combine bioabsorgable reinforcement with tubular foam structures. However, there is clear motivation. Vyakarnam et al, and if needed the Japanese patent, clearly suggest reinforcement of a sponge to be implanted. If reinforcement was not advantageous, the references would not have suggested using reinforcement. It is clear from Vacanti et al that reinforcement with artificial means can be used event when using smooth muscle cells that produce elastin. The fact that the Japanese patent may not use *ex vivo* tissue engineering does not make the rejection untenable since Naughton et al suggest *in vitro* growing of cells in a matrix to produce tissue. The references are

combined together, and must be considered together as a whole rather than each alone.

Bell et al (4,546,500) is made of record to further show reinforcement of engineered vessels.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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5/24/06

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